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PATENT Docket No.: 082368-002810US Client Ref. No.: ONC-A0216P2-US

TOWNSEND and TOWNSEND and CREW LLP

By: /Megan McCoy/ Megan McCoy

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Examiner:

Rawlings, Stephen L.

Yusuke NAKAMURA, et al.

Art Unit: 1643

Confirmation No.: 8925

Application No.: 10/529,381 Filed: November 28, 2005

For: GENES AND POLYPEPTIDES RELATING TO PROSTATE CANCERS

OF PATENT TERM ADJUSTMENT DETERMINATION

Customer No.: 20350

UNDER 37 C.F.R. § 1.705(b)

REQUEST FOR RECONSIDERATION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Commissioner:

Pursuant to 37 C.F.R. § 1.705(b), Applicants respectfully request reconsideration of the patent term adjustment determination. This request is accompanied by the fee set forth in §1.18(e) and a statement of facts as required under 37 C.F.R. § 1.705(b)(2).

In view of the following it is respectfully requested that Applicants be granted a minimum patent term adjustment of 498 days, with an additional term to be added if the patent issues after May 19, 2009 (which is the Tuesday prior to 28 weeks after the mailing date of the Notice of Allowance).

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Under 37 C.F.R. § 1.705(b)

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Statement of Facts as required under 37 C.F.R. § 1.705(b)(2)

The correct patent term adjustment is 498 days, not 326 days as stated on the Determination of Patent Term Adjustment under 35 U.S.C.§ 154(b) mailed on November 6, 2008 with the Notice of Allowance.

The period of adjustment under § 1.702(a) is 331 days ("A delay").

The period of adjustment under § 1.702(b) is to be determined when the instant application issues. The effective period of adjustment under 37 C.F.R. § 1.702(b) is 172 days ("B delay").

The period adjustment under § 1.704(a) is 5 days ("applicant delay"). The period of adjustment under § 1.703(f) is 498 days.

The Relevant Dates as Specified in 37 C.F.R. §§ 1.703(a)-(e) and the Adjustment Specified in 37 C.F.R. § 1.703(f)

1. § 1.703(a)

Applicants submit that the Office did correctly calculate the term adjustments to include the term adjustments that Applicants are entitled under 37 CFR § 1.703(a)(1) and § 1.703(a)(3) to be 331 days. (See Exhibit A, attached hereto) The relevant § 1.703(a)(1) dates are shown below.

| Filing Date | 14-month Date | Date of 1st Restriction Requirement | Days over 14 months (§ 1.703(a)(1)) |
|-------------------|------------------|----------------------------------------|----------------------------------------|
| November 28, 2005 | January 28, 2007 | December 12, 2007 | 318 days |

Applicants acknowledge that the Office has correctly determined the adjustment under § 1.703(a)(3) to be 13 days as defined under § 154(b)(1)(A).

| Date of Applicant Reply | 4-month Date | Date of mailed PTO Response | Days over 4months (§ 1.703(a)(3)) |
|-------------------------|------------------|--------------------------------|--------------------------------------|
| June 18, 2008 | October 18, 2008 | October 31, 2008 | 13 days |

Applicants, however, respectfully request an additional period of adjustment equal to the number of days, if any, in the period beginning on the day after the date that is four months after the date on which the issue fee will be paid and all outstanding requirements are Application No.: 10/529.381

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satisfied and ending on the date the patent issues. See, 35 U.S.C. §154(b)(1)(A)(iv), 37 C.F.R. § 1.702(a)(4) and § 1.703(a)(6).

2. § 1.703(b)

The Office failed to issue a patent within three years of the actual filing date of the above-referenced application. The period of adjustment under 37 C.F.R. § 1.702(b) begins on the day after the date that is three years from the filing date of the instant application, November 28, 2008, and ends on the day the patent is issued. The Notice of Allowance was mailed on November 6, 2008. If the patent issues approximately 28 weeks from the mailing of the Notice of Allowance, the estimated date of issuance is May 19, 2009 (rounded to nearest Tuesday).

Thus, the effective period of adjustment under 37 C.F.R. § 1.702(b) is 172 days, i.e., from November 28, 2008 to May 19, 2009 as shown in the table below.

| Filing Date | 3-year Date | Date of Notice of Allowance | | |
|----------------------|----------------------|--------------------------------|--------------|----------|
| November 28, 2005 | November 28, 2008 | November 6, 2008 | May 19, 2009 | 172 days |

3. § 1.703(c)-(e)

There are no relevant dates as specified under §§ 1.703(c)-(e)

Overlapping periods under § 1.703(a)-(e)

Applicants have calculated overlapping periods in accordance with Wyeth v. Dudas (Case No. 07-1492, D.D.C. 2008). Thus, the periods of delay under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §1.54(b)(1)(B) overlap only if they occur on the same calendar day or days.

There are no overlapping periods under §§ 1.703(a)-(e).

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5. § 1.703(f)

The period of adjustment under 37 C.F.R. § 1.702(f) is as follows:

| Type "A" delay: | 331 days |
|----------------------|----------|
| Type "B" delay: | 172 days |
| "A" and "B" overlap: | 0 days |
| Adjusted | 503 days |

As discussed above, Applicants respectfully request an additional period of adjustment equal to the number of days, if any, under 37 C.F.R. § 1.703(a)(6). Any such period of adjustment under 37 C.F.R. § 1.703(a)(6) begins on May 19, 2009 will not overlap with a period of adjustment under 37 C.F.R. § 1.702(b).

Reduction of Period of Adjustment of Patent Term Under 37 C.F.R. §1.704

The correct period of adjustment under § 1.704(a) is <u>5 days</u> as indicated by the Patent Term Adjustment History (see Exhibit A).

Terminal disclaimer

The instant application is not subject to a terminal disclaimer.

PATENT TERM ADJUSTMENT DETERMINATION

Applicants are entitled to 498 days of patent term adjustment, i.e., [503 days (A delay + B delay)] minus [5 days (applicant delay)]. Applicants are also entitled to any period of adjustment under 37 C.F.R. § 1.703(a)(6).

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CONCLUSION

Please charge the fee set forth in 37 C.F.R. §1.18(e) (\$200.00) to Deposit Order Account No. 20-1430. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 20-1430.

Based on the foregoing, Applicants respectfully request reconsideration of the patent term adjustment determination.

Respectfully submitted,

and Shas

Carol P. Johns Reg. No. 50,463

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, Eighth Floor San Francisco, California 94111-3834 Tel: (415) 576-0200 Fax: (415) 576-0300 Attachments: Exhibit A (2 pages)

CPJ:m4m

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EXHIBIT A

| 10/529,381 | GENES AND PO | LYPEPTIDES RE | LATING TO PROSTATE CANCERS | | 02-04- 2009::13:40:12 |
|----------------|---------------------|----------------------|----------------------------------|------|--------------------------|
| Patent Terr | n Adjustments | | | | |
| Patent Term | Adjustment (PTA) fo | or Application Nur | nber: 10/529,381 | | |
| Filing or 371(| c) Date: | 11-28-2005 | USPTO Delay (PTO) Delay (days) | : | 331 |
| Issue Date of | Patent: | - | Three Years: | | - |
| Pre-Issue Pet | itions (days): | +0 | Applicant Delay (APPL) Delay (da | ys): | 5 |
| Post-Issue Pe | titions (days): | +0 Total PTA (days): | | | 326 |
| USPTO Adjust | tment(days): | +0 | Explanation Of Calculations | | |
| Patent Terr | n Adjustment F | listory | | | |
| Date | Contents Desc | ription | PTO(D | ays) | APPL(Days) |
| 11-06-2008 | Mail Notice of Al | lowance | | | |
| 11-05-2008 | Document Verifi | cation | | | |
| 11-05-2008 | Notice of Allowa | nce Data Verificat | ion Completed | | |
| 11-05-2008 | Case Docketed t | o Examiner in GA | U | | |
| 11-05-2008 | Examiner's Ame | ndment Commun | ication | | |
| 10-15-2008 | Examiner Interv | iew Summary Red | cord (PTOL - 413) | | |
| 11-04-2008 | Mail Examiner Ir | nterview Summar | y (PTOL - 413) | | |
| 10-15-2008 | Examiner Interv | iew Summary Red | cord (PTOL - 413) | | |
| 10-31-2008 | Mail Examiner Ir | nterview Summar | y (PTOL - 413) | | |
| 10-31-2008 | Mail Examiner Ir | nterview Summar | y (PTOL - 413) | | |
| 10-31-2008 | Mail Miscellaneo | us Communicatio | n to Applicant | 13 | |
| 10-31-2008 | Miscellaneous Ad | ction with SSP | | • | |
| 10-15-2008 | Examiner Interv | iew Summary Red | cord (PTOL - 413) | 企 | |
| 10-01-2008 | Examiner Interv | iew Summary Re | cord (PTOL - 413) | 4 | |
| 07-22-2008 | Date Forwarded | to Examiner | | 1 | |
| 06-23-2008 | Supplemental Re | esponse | | | 5 |
| 06-18-2008 | Oath or Declarat | tion Filed (Includi | ng Supplemental) | | 4 |
| 07-11-2008 | Date Forwarded | to Examiner | | | 4 |
| 06-18-2008 | Response after I | Non-Final Action | | | 4 |
| 02-11-2008 | Amendment Cro | ssed in Mail | | | |
| 03-19-2008 | Mail Non-Final R | ejection | | | |
| 03-14-2008 | Non-Final Reject | ion | | | |
| 12-19-2006 | Information Disc | closure Statement | considered | | |
| 11-28-2005 | Information Disc | closure Statement | considered | | |
| 02-28-2008 | Case Docketed t | o Examiner in GA | .u | | |
| 01-17-2008 | Date Forwarded | to Examiner | | | |
| 01-14-2008 | Response to Ele | ction / Restriction | Filed | | |
| 12-12-2007 | Mail Restriction | Requirement | | 318 | |
| 12-10-2007 | Requirement for | Restriction / Elec | tion | 1 | |
| 06-28-2007 | Case Docketed t | o Examiner in GA | .U | 1 | |
| 12-19-2006 | Information Disc | closure Statement | (IDS) Filed | 1 | |

EXHIBIT A -- cont.

| 12-19-2006 | Information Disclosure Statement (IDS) Filed | * | |
|------------|------------------------------------------------------------------------------------------------------|---|--|
| 05-10-2006 | IFW TSS Processing by Tech Center Complete | 1 | |
| 11-28-2005 | Information Disclosure Statement (IDS) Filed | 1 | |
| 11-28-2005 | Information Disclosure Statement (IDS) Filed | • | |
| 11-28-2005 | Preliminary Amendment | 4 | |
| 05-10-2006 | Case Docketed to Examiner in GAU | • | |
| 04-22-2006 | Cleared by OIPE CSR | 1 | |
| 04-19-2006 | Cleared by OIPE CSR | 1 | |
| 04-19-2006 | Cleared by OIPE CSR | • | |
| 11-28-2005 | 371 Completion Date | 1 | |
| 04-17-2006 | Application Dispatched from OIPE | * | |
| 04-17-2006 | Notice of DO/EO Acceptance Mailed | 企 | |
| 11-28-2005 | Additional Application Filing Fees | • | |
| 11-28-2005 | Information Disclosure Statements | 1 | |
| 11-28-2005 | A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic | 1 | |
| | | | |

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